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UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

ROBERT REID, on Behalf of Himself and All Others Similarly Situated,

Plaintiff,

v.

JOHNSON & JOHNSON, and MCNEIL NUTRITIONALS, LLC

Defendants.

Case No: 3:11-cv-01310 L POR
Pleading Type: Class Action

OPPOSITION TO DEFENDANTS' MOTION TO DISMISS

Judge: Hon. M. James Lorenz
Date: September 19, 2011
Time: 10:30 a.m.
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INTRODUCTION

For more than a decade Johnson & Johnson, and its McNeil division (collectively "McNeil"), have been misleadingly marketing Benecol margarine as *Proven to Reduce Cholesterol* and containing *No Trans Fat*, despite being made with artificial trans fat, a toxic substance structurally similar to plastic, which *increases* blood cholesterol more than any other nutrient and causes disease and premature death. Along the way, McNeil violated regulations promulgated pursuant to the Federal Food, Drug and Cosmetic Act, rendering Benecol not only deceptive under California law, but also misbranded under the FDCA. For the reasons discussed herein, Plaintiff Robert Reid respectfully requests that the Court deny McNeil's Motion to Dismiss the Complaint.

ARGUMENT

I. PLEADING STANDARD

"In alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b). The purpose of Rule 9(b) is to ensure the allegations are "specific enough to give defendants notice of the particular misconduct which is alleged to constitute the fraud charged so that they can defend against the charge and not just deny that they have done anything wrong." *Semegen v. Weidner*, 780 F.2d 727, 731 (9th Cir. 1985). "A pleading is sufficient under rule 9(b) if it identifies the circumstances constituting fraud so that a defendant can prepare an adequate answer from the allegations." *Moore v. Kayport Package Express, Inc.*, 885 F.2d 531, 540 (9th Cir. 1989). While the heightened pleading standard set out by Rule 9(b) applies to claims for violation of the UCL, FAL, or CLRA "grounded in fraud," *see Vess v. Ciba-Geigy Corp. USA*, 317 F.3d 1097, 1103-06 (9th Cir. 2009), "the specificity required [under Rule 9(b)] for the misrepresentation element is not required for the damage and reliance elements." *Meram v. MacDonald*, 2006 U.S. Dist. LEXIS 79069, at *13 (S.D. Cal. Oct. 13, 2006) (Lorenz, J.) (discussing common law fraud claim); *accord* Fed. R. Civ. P. 9(b) ("conditions of person's mind may be averred generally"). Thus, to comply with Rule 9(b)'s heightened pleading requirement, a plaintiff need only plead "the circumstances constituting fraud . . . with particularity." *Meram*, 2006 U.S. Dist. Lexis 79069, at *13. "In this regard, it is sufficient to plead items such as the time, place and nature of the alleged fraudulent activities." *Id.* Moreover, the "Rule 9(b) particularity requirements must be read in

harmony with Rule 8's requirement of a 'short and plain' statement of the claim." *Baas v. Dollar Tree Stores, Inc.*, 2007 U.S. Dist. LEXIS 65979, at *5 (N.D. Cal. Aug. 29, 2007). Finally, the requirements of Rule 9(b) "may be relaxed with respect to matters within the opposing party's knowledge. In such situations, plaintiffs cannot be expected to have personal knowledge of the relevant facts." *Neubronner v. Milken*, 6 F.3d 666, 672 (9th Cir. 1993).

II. PLAINTIFF'S CLAIMS ARE NOT EXPRESSLY PREEMPTED

A. Statutory Scheme

Pursuant to the Supremacy Clause, federal law preempts state law when Congress enacts a statute that explicitly preempts state law. *See Chae v. SLM Corp.*, 593 F.3d 936, 941 (9th Cir. 2010). There are two "cornerstones" of preemption jurisprudence:

> First, the purpose of Congress is the ultimate touchstone in every pre-emption case. . . . Second, in all pre-emption cases, and particularly in those in which Congress has legislated in a field which the States have traditionally occupied, we start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.

Wyeth v. Levine, 129 S. Ct. 1187, 1194-95 (2009) (internal quotations, citations and alterations omitted) (citing *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996); *Retail Clerks v. Schermerhorn*, 375 U.S. 96, 103 (1963); *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)). In short, "Congress does not cavalierly pre-empt state-law causes of action." *Medtronic*, 518 U.S. at 485. This strong presumption against preemption requires courts give express preemption clauses a "narrow reading." *See Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 518 (1992). Moreover, where there are "plausible alternative reading[s]" of an express preemption provision, courts "have a duty to accept the reading that disfavors pre-emption." *Bates v. Dow Agrosciences, LLC*, 544 U.S. 431, 449 (2005).

The FDCA, 21 U.S.C. §§ 301 *et seq.*, empowers the Food and Drug Administration to (a) protect public health by ensuring that "foods are safe, wholesome, sanitary, and properly labeled," 21 U.S.C. § 393(b)(2)(A); (b) promulgate regulations to implement the statute, *see* 21 C.F.R. § 7 *et seq.*; and (c) enforce its regulations through administrative proceedings, *id.* The Act prohibits the distribution and sale of misbranded foods. *See* 21 U.S.C. §§ 331(a)-(c), (g), (k). Foods are deemed misbranded when they meet one of the definitions for being misbranded pursuant to 21 U.S.C. § 343. Congress enacted the Nutrition Labeling and Education Act, Pub. L. No. 101-535, § 6(a), 104 Stat.

2353 (1990), to "clarify and to strengthen [FDA's] authority to require nutrition labeling on foods, and to establish the circumstances under which claims may be made about the nutrients in foods." *Nat'l Council for Improved Health v. Shalala*, 122 F.3d 878, 880 (10th Cir. 1997) (quoting H.R. Rep. No. 101-538, at 7 (1990), *reprinted in* 1990 U.S.C.C.A.N. 3336, 3337). In passing the NLEA, Congress sought to "create uniform national standards regarding the labeling of food and to prevent states from adopting inconsistent requirements with respect to the labeling of nutrients." *Farm Raised Salmon Cases*, 42 Cal. 4th 1077, 1086 (2008) (finding state law claim involving artificial food color not preempted and citing Remarks of Rep. Waxman, 136 Cong. Rec. 5840 (daily ed. July 30, 1990), debate on H.R. No. 3562, 101st Cong., 2d Sess.). The NLEA introduced the now-familiar Nutrition Facts panel and amended the FDCA to preempt some state labeling requirements not identical to those promulgated under specific portions of § 343. *See* 21 U.S.C. § 343-1.

The strong presumption against preemption "applies with particular force when Congress has legislated in a field traditionally occupied by the States." *Altria Group, Inc. v. Good*, 555 U.S. 70, 77 (2008) (citing *Medtronic*, 518 U.S. at 485)."[C]laims[] rooted in California's consumer-protection laws[] fall in an area that is traditionally within the state's police powers to protect its own citizens. 'Because consumer protection law is a field traditionally regulated by the states, compelling evidence of an intention to preempt is required in this area.'" *Aguayo v. U.S. Bank*, 2011 U.S. App. LEXIS 15806, at *7 (9th Cir. Aug. 1, 2011) (quoting *Gen. Motors Corp. v. Abrams*, 897 F.2d 34, 41-42 (2d Cir. 1990)); *see also Law v. General Motors Corp.*, 114 F.3d 908, 909-10 (9th Cir. 1997) ("Given the importance of federalism . . . we entertain a strong presumption that federal statutes do not preempt state laws; particularly those laws directed at subjects—like health and safety—'traditionally governed' by the states." (citation omitted)); *Farm Raised Salmon Cases*, 42 Cal. 4th at 1087-88 ("[C]onsumer protection laws such as the UCL, false advertising law, and CLRA, are within the states' historic police powers and therefore are subject to the presumption against preemption. Laws regulating the proper marketing of food, including the prevention of deceptive sales practices, are likewise within states' historic police powers." (internal quotations, citation and alterations omitted)).

B. *No Trans Fat* and *No Trans Fatty Acids*

Mistakenly relying on 21 C.F.R. § 101.9(c)(2)(ii)'s provision that manufacturers express in the

Nutrition Facts Box amounts of trans fat below 0.5 grams per serving as "0g," McNeil ignores that its front-label advertisements *No Trans Fat* and *No Trans Fatty Acids* "expressly or implicitly characterize[] the level of a nutrient," 21 C.F.R. § 101.13(b), and are therefore nutrient content claims governed by FDCA § 343(r) and its implementing regulations. *See* 21 U.S.C. §§ 343(r)(1)(A), (r)(2).

Under the FDCA, "a nutrient content claim[] may not be made on the label or in the labeling of foods unless the claim is made in accordance with this regulation and with the applicable regulations in subpart D of this part . . . ." 21 C.F.R. § 101.13(b). Subpart D prescribes requirements for a handful of specific, itemized nutrient content claims, but does not include a definition for a *No Trans Fat* claim. *See id.* §§ 101.54-101.69. Accordingly, Benecol "bears an unauthorized nutrient content claim ('No Trans Fat') which has not been defined by FDA." FDA Warning Letter to BestLife International, dated February 4, 2008 (the "BestLife Letter").[1]

In making an unauthorized nutrient content claim, McNeil violates 21 C.F.R. § 101.13(b), rendering Benecol misbranded.[2] 21 U.S.C. § 343(r)(1)(A). Accordingly, Mr. Reid's claims are not preempted. *See Mason v. Coca-Cola Co.*, 2010 U.S. Dist. LEXIS 65107, at *8 (D.N.J. June 30, 2010). ("Plaintiffs merely allege that Defendant failed to abide by the federal labeling requirements and, in doing so, misled Plaintiffs as a matter of state law. Nothing in the language of the statute expressly preempts a state claim for consumer fraud based on a failure to follow federal labeling regulations."); *Smajlaj v. Campbell Soup Co.*, 2011 U.S. Dist. LEXIS 30852, at *12 (D.N.J. Mar. 23, 2011) ("because Plaintiffs' claims mirror the federal requirements, they are not preempted").

The cases McNeil relies on are inapposite because each concerned the front-label statement that a product contained "0g trans fat per serving," a claim those courts held was permitted pursuant to

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[1] *See* Request for Judicial Notice ("RJN"), Ex. A. *C.f.* RJN Ex. B (FDA Warning Letter to Cytosport, dated June 29, 2011 (stating that "[o]nly the claims specified in 21 CFR 101.62 may be made for fat or fatty acids," and determining that "Trans-Fat Free" is an unauthorized nutrient content claim).

[2] Even if a *No Trans Fat* nutrient content claim were permitted, its use on Benecol's label would violate 21 C.F.R. § 101.13(f), which prohibits such claims if they are "unduly prominent in type style compared to the statement of identity" ("statement of identity" is defined at 21 C.F.R. § 101.3(b)). Because the *No Trans Fat* claim appears in a bold, red type style, adjacent to a heart graphic, all encompassed in a "stamp" on the front label, a jury could find it is "unduly prominent" compared to the green "55% Vegetable Oil" statement of identity in the upper right corner. *See, e.g.*, Compl. Ex. A.

21 C.F.R. § 101.13(i)(3). *See* Mot. 13. Notwithstanding the logic of McNeil's argument that in "common parlance" the words "zero" and "no" are "functionally equivalent," *id.* 12, FDA regulations draw a qualitative distinction between them when used to advertise a food's ingredients, as the FDA warning letter makes clear.

C. *Proven to Reduce Cholesterol*

The claim that a food is *Proven to Reduce Cholesterol* is a health claim because it "expressly or by implication . . . characterizes the relationship of any substance to a disease or health-related condition." 21 C.F.R. § 101.14(a)(1).

> No expressed or implied health claim may be made on the label or in labeling for a food . . . unless: (1) The claim is specifically provided for in subpart E of this part; and (2) The claim conforms to all general provisions of this section as well as to all specific provisions in the appropriate section of subpart E of this part . . . .

Id. § 101.14(e). Thus, McNeil may only claim Benecol is *Proven to Reduce Cholesterol* in accordance with a regulation set out in 21 C.F.R. §101.70-101.83, governing Specific Requirements for Health Claims. The regulation governing plant stanol ester health claims provides: "*Optional information.* . . . The claim may state that the relationship between intake of diets that include plant sterol/stanol esters and reduced risk of heart disease is through the intermediate link of 'blood cholesterol' or 'blood total and LDL cholesterol.'" *Id.* § 101.83(d)(2). The regulation does ***not*** authorize McNeil's advertisement that Benecol is *Proven to Reduce Cholesterol*, which ***no FDA regulation authorizes*** and § 101.14(e) ***expressly prohibits***. Moreover, because the regulation provides that "the *claim* may state" the optional information, McNeil violates § 101.83(d)(2) by giving the optional information "prominent placement on a banner," appearing in "much larger font size . . . and [with] other text effects" than the health claim, thereby "clearly distinguish[ing]" the *Proven to Reduce Cholesterol* advertisement from the health claim. *See* FDA Warning Letter to General Mills, Inc., dated May 5, 2009 (the "Cheerios Letter"), RJN Ex. C. Accordingly, the NLEA does not expressly preempt Plaintiffs' claims that this advertisement is false and misleading under state law.[3]

[3] McNeil's reliance on 21 C.F.R. § 101.14(d)(2)(i), is misplaced. *See* Mot. 14. All that section says is "[w]hen [the] FDA has adopted a regulation in subpart E of this part providing for a health claim, firms may make claims based on the regulation . . . provided that" seven criteria are met. In other

D. Heart Graphics

Heart symbols and vignettes are implied health claims, 21 C.F.R. § 101.14(a)(1), and must be used in connection and compliance with an authorized health claim, *id.* § 101.14(e). Benecol's label is swathed in hearts, including a prominent one around the product name and tag line, a heart associated with the unauthorized *No Trans Fat* nutrient content claim, and several others. *See* Compl. Exs. A-D. Because these hearts are made in connection with statements for which the FDA has not issued a health claim (e.g., *No Trans Fat*), or which violate an existing health claim regulation (e.g., *Proven to Reduce Cholesterol*), they are prohibited. *See* § 101.14(e)(1)-(2). Accordingly, Plaintiff's challenges to the heart symbols and vignettes are not preempted. *See generally Zeisel v. Diamond Foods, Inc.*, 2011 U.S. Dist. LEXIS 60608 (N.D. Cal. June 7, 2011) (certifying class of consumers who purchased walnuts that were alleged to be misleading in part because of the inclusion of a heart symbol adjacent to a challenged health claim).

E. The Plant Stanol Ester Health Claim

When on September 8, 2000 the FDA approved a plant stanol ester health claim, its regulation setting out the requirements, 21 C.F.R. § 101.83,[4] had a preemptive effect on the States pursuant to the NLEA.[5] "Although section 343-1 speaks in terms of what states may *not* do, by negative implication, section 343-1 also expresses what states *may* do, i.e., states *may* establish their own requirements pertaining to the labeling of [nutrient content claims] so long as their requirements are identical to those contained in the FDCA in section 343[(r)]." *Farm Raised Salmon Cases*, 42 Cal. 4th at 1086 (citations omitted). Thus while the FDA's interim final rule preempted state requirements preventing manufacturers from using the claim set out in § 101.83—that "*[f]oods containing at least 1.7 g per*

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words, McNeil's *Proven to Reduce Cholesterol* claim must still comply with § 101.83.

[4] *See generally* Compl. ¶¶ 4, 75.

[5] The FDA has noted the preemptive effect of interim final rules. *See, e.g.*, 73 Fed. Reg. 9938, 9945-46 (Feb. 25, 2008) (interim final rule concerning health claim labeling requirements for beta-glucan soluble fiber and reduced risk of CHD "has a preemptive effect on State law"); 68 Fed. Reg. 39831, 39832 (July 3, 2003) (same with respect to health claim concerning D-tagatose and reduced risk of dental cavities). *Accord Kargman v. Sullivan*, 1982 U.S. Dist. LEXIS 13820, at *9-10 (D. Mass. July 16, 1982) (noting preemptive effect of agency's interim rule).

serving of plant stanol esters, eaten twice a day with meals for a total daily intake of at least 3.4 g, as part of a diet low in saturated fat and cholesterol, may reduce the risk of heart disease"—the interim final rule also permitted state law to prohibit the use of other claims, like the one on Benecol's label. Compl. ¶¶ 84-86.[6] Accordingly, Plaintiff's claims are not preempted.

McNeil argues, however, that a 2003 FDA letter to an unrelated food manufacturer, Cargill, provides an exception to the rule of preemption under the NLEA because the letter supposedly "confirmed FDA's intent *not* to enforce the IFR," Mot. 4. But the letter actually says:

> This letter is in response to your letter . . . ***requesting*** that FDA issue a letter stating its intention not to enforce certain requirements in the interim final rule (IFR) authorizing a health claim for plant sterol/stanol esters and reduced risk of heart disease (CHD) (21 CFR 101.83). Citing new scientific evidence and comments submitted to FDA . . . , you ***requested*** that FDA exercise enforcement discretion until such time as a final rule is issued. . . . Based upon ***preliminary review*** of the comments and additional scientific evidence, FDA intends ***to consider*** the exercise of enforcement discretion, pending publication of the final rule, with respect to certain requirements of the health claim. The agency ***will consider*** exercising enforcement discretion with regard to the use of a claim about reduced risk of CHD in the labeling of a phytosterol-containing food . . . if: [certain conditions are met]. . . . FDA is developing a final rule on this health claim and intends to publish it as expeditiously as possible. . . . In the interim . . . , ***the agency intends to develop*** and promptly issue guidance that will contain FDA's enforcement discretion criteria for health claims for phytosterols and reduced risk of CHD.

McNeil RJN Ex. C (emphasis added). Thus, the FDA was not *agreeing* it would refrain from enforcing § 101.83, or setting out "enforcement criteria," as McNeil asserts, but merely *considering* it. But even if the FDA had decided to exercise its enforcement discretion, that would still not preempt Plaintiff's claims: "it is federal *law* which preempts contrary state law; nothing short of federal law can have that effect." *Fellner v. Tri-Union Seafoods, L.L.C.*, 539 F.3d 237, 243 (3d Cir. 2008).

"It is well-established that both federal statutes and federal regulations properly adopted in accordance with statutory authorization form the basis of federal law." *Von Koenig v. Snapple Bev.*

[6] Plaintiff alleges that, "for over a decade, [Defendants] ha[ve] packaged Benecol with an improper plant stanol health claim," Compl. ¶ 4. Contrary contentions in McNeil's brief may not be considered on a motion to dismiss. *See* Mot. 3-4 ("McNeil began selling Benecol with the claims approved by the IFR and codified at 21 C.F.R. § 101.83. * * * The formulation and label of Benecol were thereafter changed, as McNeil lowered the amount of plant stanol esters in the product."). *See generally Wright v. Gen. Mills, Inc.*, 2009 U.S. Dist. LEXIS 90576, at *11 (C.D. Cal. Sept. 30, 2009) (Lorenz, J.) (on motion to dismiss, court may not look beyond the complaint at facts asserted in memorandum).

Corp., 713 F. Supp. 2d 1066, 1074 (E.D. Cal. 2010) (citations omitted). While "in appropriate circumstances, federal agency action taken pursuant to statutorily granted authority short of formal, notice and comment rulemaking may also have preemptive effect over state law," *Holk v. Snapple Bev. Corp.*, 575 F.3d 329, 340 (3d Cir. 2009) (citing *Fellner*, 539 F.3d at 244), that is limited to situations where Congress "provides for a relatively formal administrative procedure tending to foster the fairness and deliberation that should underlie a pronouncement of such force," *see Von Koenig*, 713 F. Supp. 2d at 1074 (quoting *United States v. Mead Corp.*, 533 U.S. 218, 230 (2001)). *See also Holk*, 575 F.3d at 342 (inquiry into whether agency action has force of law is focused predominantly "on the process by which the agency arrived at its decision, rather than on what happened after the decision was made"). In *Holk*, the Third Circuit rejected the argument that something like the Cargill letter could preempt state law:

> We also reject Snapple's arguments that a letter from a[n] FDA official from July 2008 is entitled to weight. The letter was not issued as part of any formal rulemaking or adjudication and was not subject to notice and comment. Additionally, the FDA issued the letter in response to a question from interested parties, rather than doing so in an enforcement action. Under *Fellner*, this letter does not have the force of law.

575 F.3d at 342 n.6. Rather, when McNeil chose to make a health claim other than the one permitted under federal law—even if it did so because the FDA told Cargill the agency would "consider" its enforcement discretion—McNeil ran the risk that its non-conforming health claim would offend non-preempted state law; "while allowing private remedies based on violations of state laws identical to the FDCA may arguably result in actions that the FDA itself might not have pursued, Congress appears to have made a conscious choice not to preclude such actions." *Farm Raised Salmon Cases*, 42 Cal. 4th at 1098.[7]

[7] McNeil "concede[s] that some of the statements at issue [in the action] are outside the scope of this [preemption] framework," by "only argu[ing] that some of the statements are preempted by FDA Regulations." *See Henderson v. J.M. Smucker Co.*, 2011 U.S. Dist. LEXIS 27953, at *8-9 (C.D. Cal. Mar. 17, 2011) (emphasis added). In addition to the label claims already discussed, Mr. Reid alleges the product name, "Benecol," and the label's depiction of vegetables, are deceptive. Compl. ¶ 115 *C.f. Red v. Kraft Foods, Inc.*, 754 F. Supp. 2d 1137 (C.D. Cal. 2010) (upholding challenges to depictions of vegetables on packaging of crackers made with trans fat); *Chacanaca v. Quaker Oats Co.*, 752 F. Supp. 2d 1111, 1123-24 (N.D. Cal. 2010) (upholding challenges to depictions of healthy children, oats and nuts on packaging of granola bars made with trans fat). Plaintiff also challenges as deceptive the statement on the inside of Benecol's packaging that Benecol "contain[s] an extremely low level of

III. PLAINTIFF'S CLAIMS ARE NOT IMPLIEDLY PREEMPTED

A. Implied Preemption is Excluded by the NLEA's "Savings Clause"

"The NLEA's rule of construction concerning the scope of preemption excludes implied preemption, providing in relevant part that, '[t]he [NLEA] shall not be construed to preempt any provision of State law, unless such provision is expressly preempted under section 403A of the [FDCA].'" *Red*, 754 F. Supp. 2d 1137, 1139 (citing Pub. L. No. 101-535, § 6(c)(1), 104 Stat. 2353, 2364; *Farm Raised Salmon Cases*, 42 Cal. 4th at 1091 ("the preemptive scope of section 343-1 [sweeps] no further than the plain language of the statute itself.")).[8] Accordingly, the Court should reject McNeil's argument. Mot. 14-15.

B. There is no Conflict Because the False and Misleading Statements are Voluntary

Even if implied preemption were available, it would do McNeil no good. McNeil argues two species of implied preemption: impossibility and obstacle. Impossibility preemption "is a demanding defense," *Wyeth*, 129 S. Ct. at 1199, requiring a defendant to show that "compliance with both federal and state [law] is a physical impossibility," *Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142-43 (1963) (finding no preemption of a California food regulation). Here, there is no such "physical impossibility" because every statement Mr. Reid challenges is *voluntary*.[9] *See Chacanaca*,

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trans fat," which is "considered an insignificant amount." *See* Compl. ¶¶ 116. McNeil does not assert that any of these challenges are preempted. As a result, because a finding that some phrases are preempted "would not result in the dismissal of any claim," the Court need not necessarily "reach the preemption issue" with respect to each challenge. *See Henderson*, 2011 U.S. Dist. LEXIS 27953, at *14-15 & n.5.

[8] *See also Zeisel v. Diamond Foods, Inc.*, 2010 U.S. Dist. LEXIS 141941, at *10-11 (N.D. Cal. Sept. 3, 2010); *Red v. Kroger Co.*, 2010 U.S. Dist. LEXIS 115238, at *10-11 n.3 (C.D. Cal. Sept. 2, 2010) ("there is no implied preemption under the NLEA"); *Astiana v. Ben & Jerry's Homemade, Inc.*, 2011 U.S. Dist. LEXIS 57348, at *22 (N.D. Cal. May 26, 2011); *Hansen Bev. Co. v. Innovation Ventures, LLC*, 2009 U.S. Dist. LEXIS 127605, at *34 (S.D. Cal. Dec. 23, 2009); *Wright*, 2009 U.S. Dist. LEXIS 90576, at *6 (Lorenz, J.); *Pom Wonderful LLC v. Ocean Spray Cranberries, Inc.*, 642 F. Supp. 2d 1112, 1123 (C.D. Cal. 2009); *Lockwood v. Conagra Foods, Inc.*, 597 F. Supp. 2d 1028,1031-33 (N.D. Cal. 2009).

[9] McNeil frequently cites the requirement under 21 C.F.R. § 101.9(c)(2)(ii) that food manufacturers express trans fat amounts below 0.5 grams per serving as "0g" *in the Nutrition Facts Panel*, but that is not at issue. Mr. Reid does not challenge McNeil's disclosure of trans fat in the Nutrition Facts panel, but instead only the voluntary statements made elsewhere on Benecol's label and packaging. *See Henderson*, 2011 U.S. Dist. LEXIS 27953, at *12 ("Defendant also argues that FDA Regulations

752 F. Supp. 2d at 1117. For the same reason, enforcing Plaintiff's claims by enjoining the use of voluntary statements presents no obstacle to uniform labeling. Unlike state laws *requiring* lactose intolerance warnings on milk labels, *Mills v. Giant of Md., LLC*, 441 F. Supp. 2d 104 (D.D.C. 2006), or the name and address of canners and importers on food labels, *Goya de P.R., Inc. v. Santiago*, 59 F. Supp. 2d 274 (D.P.R. 1999), which impede consistent nationwide food labeling, "[s]tate-law prohibitions on false statements of material fact do not create diverse, nonuniform, and confusing standards." *Cipollone*, 505 U.S. at 529 (internal quotations omitted). Additionally, the NLEA's savings clause means claims under state law that are not expressly preempted cannot be an "obstacle" to congressional objectives for uniform food labeling. *C.f. Wyeth*, 129 S. Ct. at 1200.

IV. MR. REID HAS STANDING

A. UCL and FAL

California's UCL prohibits any "unlawful, unfair or fraudulent business act or practice and unfair, deceptive, untrue or misleading advertising . . . ." Cal. Bus. & Prof. Code § 17200. "Its coverage is sweeping, embracing anything that can properly be called a business practice and that at the same time is forbidden by law." *Cel-Tech Commc'ns, Inc. v. Los Angeles Cellular Tel. Co.*, 20 Cal. 4th 163, 180 (1999) (internal quotations and citations omitted). The FAL makes it unlawful for a business to disseminate any statement "which is untrue or misleading, and which is known, or which by the exercise of reasonable care should be known, to be untrue or misleading . . . ." Cal. Bus. & Prof. Code § 17500. "Any violation of the false advertising law necessarily violates the UCL." *Henderson v. Gruma Corp.*, 2011 U.S. Dist. LEXIS 41077, at *7 (C.D. Cal. Apr. 11, 2011) (internal quotations omitted) (citing *Williams v. Gerber Prods. Co.*, 552 F.3d 934 (9th Cir. 2008)).

Mr. Reid has standing under the UCL and FAL if he has "suffered injury in fact" and "lost money or property as a result of the unfair competition." *See* Cal. Bus. & Prof. Code §§ 17204, 17535. Proposition 64 "imposes an actual reliance requirement on plaintiffs prosecuting a private enforcement action *under the UCL's fraud prong*," *In re Tobacco II Cases*, 46 Cal. 4th 298, 326 (2009) (emphasis

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require it to list the trans fat content as zero when it is only present in trace amounts. This reasoning suggests a false choice which the FAC's prayer for relief does not require.").

added). In such cases, "plaintiffs who can truthfully allege they were deceived by a product's label into spending money to purchase the product, and would not have purchased it otherwise, have 'lost money or property' within the meaning of Proposition 64 and have standing to sue." *Kwikset Corp. v. Super. Ct.*, 51 Cal. 4th 310, 317 (2011).

Reliance is proven by showing defendant's "misrepresentation or nondisclosure was an 'immediate cause' of the plaintiff's injury-producing conduct." *See Tobacco II*, 46 Cal. 4th at 326 (citation omitted). "Plaintiffs are not required to plead that the fraudulent conduct was the only, predominant, or even decisive factor in influencing their conduct," *In re Toyota Motor Corp. Unintended Acceleration Mktg. Litig.*, 2011 U.S. Dist. LEXIS 52529, at *123 (C.D. Cal. May 13, 2011). Instead, "[i]t is enough that the representation has played a substantial part, and so has been a substantial factor in influencing [plaintiff's] decision." *Tobacco II*, 46 Cal. 4th at 326 (quotations and citation omitted). Moreover, "reliance will be presumed if the alleged misrepresentation or omission is judged to be 'material,' such that 'a reasonable man would attach importance to its existence or nonexistence in determining his choice of action in the transaction in question.'" *Martinez v. Welk Group, Inc.*, 2011 U.S. Dist. LEXIS 58718, at *20 (S.D. Cal. June 2, 2011) (quoting *Tobacco II*, 46 Cal. 4th at 327). Finally, "[w]hen misrepresentations and false statements were part of an extensive and long-term advertising campaign, Plaintiffs need not 'demonstrate individualized reliance on specific misrepresentations or false statements.'" *In re Toyota Motor Corp.*, 2011 U.S. Dist. LEXIS 52529, at *124 (quoting *Tobacco II*, 46 Cal. 4th at 327).

1. Because it is not Grounded in Fraud, Mr. Reid's "Unlawful" UCL Claim Requires Neither Particularity nor Reliance

"By proscribing 'any unlawful' business practice, section 17200 'borrows' violations of other laws and treats them as unlawful practices that the [UCL] makes independently actionable." *Cel-Tech*, 20 Cal. 4th at 180 (internal quotations omitted) (citing *State Farm Fire & Cas. Co. v. Super. Ct.*, 45 Cal. App. 4th 1093, 1103 (1996) (citation omitted)). While allegations of fraud are subject to Rule 9(b)'s heightened pleading standard, "[f]raud is not an essential element of a UCL claim," *Morris v. BMW of N. Am., LLC*, 2007 U.S. Dist. LEXIS 85513, at *14 (N.D. Cal. Nov. 7, 2007) (citation omitted).

In California, the elements of fraud are (1) misrepresentation, (2) knowledge of falsity, (3) intent to defraud (4) justifiable reliance, and (5) damage. *See Kearns v. Ford Motor Co.*, 567 F.3d 1120, 1126 (9th Cir. 2009). Under the FDCA, a person found to have violated 21 U.S.C. § 331 by selling misbranded food is guilty of a misdemeanor. *See* 21 U.S.C. § 333(a)(1). "An article may be misbranded pursuant to the misdemeanor provision 'without any conscious fraud at all . . . .'" *United States v. Watkins*, 278 F.3d 961, 964 (9th Cir. 2002) (quoting *United States v. Dotterweich*, 320 U.S. 277, 281 (1943)). Thus, to establish McNeil's misbranding, "plaintiff[] would be absolved from having to establish scienter and an intent to defraud, the two pivotal elements of fraud. Accordingly, plaintiff['s] [misbranding] claims do not 'sound in fraud,' and plaintiff['s] averments that rely on the FDCA and Sherman Laws need only satisfy Rule 8(a), not Rule 9(b)."[10] *See In re Actimmune Mktg. Litig.*, 2010 U.S. Dist. LEXIS 90480, at *28 (N.D. Cal. Aug. 31, 2010).

Just as Mr. Reid's "unlawful" prong claim predicated on FDCA and Sherman Law violations does not require heightened pleading, "[t]he claim . . . that Defendant has engaged in unlawful conduct under the UCL, does not *require* reliance." *Aho v. Americredit Fin. Servs.*, 2011 U.S. Dist. LEXIS 80426, at *25-26 (S.D. Cal. July 25, 2011) (emphasis added) (citing *Lewis v. Robinson Ford Sales, Inc.*, 156 Cal. App. 4th 359, 371 (2007); *Tobacco II*, 46 Cal. 4th at 325 n.17 ("There are doubtless many types of unfair business practices in which the concept of reliance, as discussed here, has no application."). *See also Kwikset*, 51 Cal. 4th at 327 n.9 (expressing "no views concerning the proper construction of the cause requirement" in UCL actions not grounded in fraud). Rather, "[f]or claims based on the 'unfair' or 'unlawful' prong of the UCL . . . courts have held that the plaintiff need not allege reliance on misrepresentations, and may allege 'causation more generally.'" *Olivera v. Am. Home Mortg. Servicing, Inc.*, 689 F. Supp. 2d 1218, 1224 (N.D. Cal. 2010).

[10] That Mr. Reid alleges violations of the FDCA and Sherman Law as predicates for his "unlawful" UCL claim, *see* Compl. ¶¶ 156-58, distinguishes his case from decisions holding *Tobacco II's* actual reliance requirement applies to claims where the predicate unlawful conduct is misrepresentation, as where a plaintiff alleges a violation of California's FAL or CLRA as a predicate "unlawful" act. *See, e.g., Hale v. Sharp Healthcare*, 183 Cal. App. 4th 1373, 1383-85 (2010) ("[t]he SAC's predicate for the claim of unlawfulness is Sharp's alleged violation of Civil Code section 1770 subdivision (a)(5), (9) and (16), provisions of the CLRA that pertain to misrepresentations and deceptive advertising").

2. Because Mr. Reid Alleges a Long-Term Advertising Campaign, He is Not Required to Plead Reliance on Specific Non-Label Advertisements

McNeil argues that Plaintiff lacks standing to challenge non-label advertising "because he does not allege that he bought Benecol based on . . . any specific advertisement or representation with the specificity required by Rule 9(b)," Mot. 19. But Mr. Reid alleges McNeil engaged in a "long-standing, multi-faceted advertising campaign . . . for more than a decade, aimed at convincing consumers that using Benecol will reduce their cholesterol," Compl.¶ 9, including "through print, web, and television advertisements, and recruit[ing] physicians to effectively 'prescribe' Benecol to their patients," *id.* ¶ 10. More specifically:

> In addition to the labels and packaging depicted in Exhibits A-D hereto, [Defendants] ha[ve] advertised and marketed Benecol through a number of channels, always repeating the common messages, that (a) because of its plant stanol esters, Benecol may be effective in reducing the risk for coronary heart disease when used as directed, (b) that Benecol is *Proven to Reduce Cholesterol*, and (c) that Benecol contains *No Trans Fat* or *No Trans Fatty Acids*.

Id. ¶ 118. Plaintiff also alleges he was a victim of McNeil's consistent Benecol messaging. For example, Mr. Reid "was periodically exposed to, saw, read and relied on" Benecol messaging "in print advertisements, for example, in free-standing inserts, and in coupons," *id.* ¶ 125; *see also id.* ¶ 128 ("Plaintiff saw, understood, and relied on the Benecol labels . . . and on related Benecol advertising, when he made his decision to purchase Benecol.").

It is axiomatic that "where, as here, a plaintiff alleges exposure to a long-term advertising campaign, the plaintiff is not required to plead with an unrealistic degree of specificity that the plaintiff relied on particular advertisements or statements," *Tobacco II*, 46 Cal. 4th at 328. Mr. Reid makes these allegations for a reason. He really did see, and really did rely on non-label advertisements about Benecol, but there is simply no way he could identify them with any particularity now because they are no longer in his possession, and may never have been. Accordingly, the Court should not require Mr. Reid to plead with an unrealistic degree of specificity that he relied on particular non-label advertisements. This would accord with both the language of *Tobacco II* and its putative purpose. *See, e.g.*, *Tobacco II*, 46 Cal. 4th at 327 (holding plaintiff was not required to plead reliance on specific statements and following an earlier tobacco case where "there was substantial evidence that Boeken

began to smoke 'for reasons that track Philip Morris's advertising at the time,'" quoting *Boeken v. Philip Morris, Inc.*, 127 Cal. App. 4th 1640, 1663 (2005)).

Also instructive are other court decisions the decisions of other courts approving allegations of a long-term advertising campaign in this context. In *Morgan v. AT&T Wireless Services, Inc.*, the Court of Appeal upheld non-specific allegations of reliance where, "[a]lthough the advertising campaign alleged in this case was not as long-term a campaign as the tobacco companies' campaign discussed in *Tobacco II*, it is alleged to have taken place *over many months*, in several different media, in which [defendant] consistently promoted its GSM/GPRS network as reliable, improving, and expanding." 177 Cal. App. 4th 1235, 1258 (2009) (emphasis added). California U.S. District Courts agree:

> Although Plaintiffs have not cited specific advertisements that predate their use of Hughes' services, each Plaintiff alleges that they subscribed to Hughes' services based on Hughes' representations, which (although roughly described) are comparable to the more recent representations, which are alleged with greater particularity. Plaintiffs are, in essence, asking this Court to make an inference that Hughes' representations have been consistent over time in certain material respects, dating back for the last several years. The Court finds this to be a reasonable inference. Because Plaintiffs have identified recent, particular representations from Hughes' marketing campaign, and alleged that they relied on similar or identical representations made at earlier times, Plaintiffs have adequately notified Hughes of the claims against it.

Walter v. Hughes Communs., Inc., 682 F. Supp. 2d 1031, 1045 (N.D. Cal. 2010) (record citations omitted) (citing *Bly-Magee v. California*, 236 F.3d 1014, 1019 (9th Cir. 2001); *Tobacco II*, 46 Cal. 4th at 328)). Similarly, four days ago, a California district court held a complaint adequately pled a *Tobacco II*-like "long-term" advertising campaign where:

> Plaintiffs allege that throughout the more than ten-year Class Period Ferrero has engaged in a long term extensive advertising campaign in which Ferrero used various forms of media to consistently convey the deceptive and misleading message that Nutella® is healthy and nutritious. Plaintiffs also list the specific statements on Nutella®'s labeling, website, television advertising, word-of-mouth, and product categorization that Plaintiffs challenge. Plaintiffs further specifically allege that they were exposed to Ferrero's long-term advertising campaign and relied on various statements from that campaign in making their decision to purchase Nutella®. Plaintiff's allegations satisfy the pleading requirements for showing reliance as set forth in the Tobacco II case.

In re Ferrero Litig., 2011 U.S. Dist. LEXIS 97488, at *6-7 (S.D. Cal. Aug. 29, 2011) (record citations omitted).

Finally, McNeil's alternative argument, that Plaintiff did not plead "but for" causation relating to non-label advertisements, *see* Mot. 19-20, is misplaced. While the *Kwikset* court held the allegation a plaintiff "would not have bought the product but for the misrepresentation" is *sufficient* to satisfy the UCL's standing requirement, *see* Mot. 19 (quoting *Kwikset*, 51 Cal. 4th at 330), it did not hold such allegations are *necessary*. Rather, the standing requirement under the UCL and FAL "focuses on the defendant's conduct and is substantially less stringent than a reliance or 'but for' causation test," *Sevidal v. Target Corp.*, 189 Cal. App. 4th 905, 924 (2010). Moreover, despite McNeil's heavy reliance on *Kwikset* to distinguish Mr. Reid's allegations, the *Kwikset* court actually "found allegations similar to Plaintiff['s] allegations were sufficient to support standing under the UCL." *See Henderson*, 2011 U.S. Dist. LEXIS 41077, at *11 (citation omitted) (comparing allegations of reliance in *Kwikset* to Henderson's allegations, which are similar to Mr. Reid's).

3. Mr. Reid Adequately Pleads Reliance on Benecol's Label

Allegations of reliance in Mr. Reid's Complaint abound. Plaintiff avers he "repeatedly purchased Benecol during the class period in reliance on [Defendants'] false representations and promises that Benecol contains an amount of plant stanol esters that may reduce the risk of heart disease when used as directed, that Benecol is *Proven to Reduce Cholesterol*, and that Benecol contains *No Trans Fat*." Compl. ¶ 11; *see also id.* ¶ 114 (

> Plaintiff purchased Benecol after being exposed to, understanding, and relying upon Defendants' advertisements, representations, claims and promises, direct or indirect, that (a) because of its plant stanol esters, Benecol may be effective in reducing the risk for coronary heart disease when used as directed, (b) that Benecol is *Proven to Reduce Cholesterol*, and (c) that Benecol contains *No Trans Fat* or *No Trans Fatty Acids*. These representations, and Benecol's overall packaging, including images of hearts and vegetables, conveyed a clear overall message that Benecol is 'good for you.' Plaintiff purchased Benecol, despite its expensive price, because of these specific and general representations and messages.).

Mr. Reid further alleges he "relied on the Benecol labels attached hereto as Exhibits A-D . . . when he made his decision to purchase Benecol." *Id.* ¶ 128. He avers he "purchased Benecol believing it had the qualities he sought based on [Defendants'] false and misleading statements," *id.* ¶ 129, but that he "lost money as a result of Defendants' deception in that Plaintiff did not receive what he paid for," *id.* ¶ 137. The Complaint also alleges "Benecol cost more than similar products without misleading

labeling, and would have cost less absent the false and misleading statements. Plaintiff purchased Benecol instead of competing products based on the false statements and misrepresentations described herein." *Id.* ¶ 134. It continues, "Plaintiff paid more for Benecol, and would have been willing to pay less, or nothing at all, if he had not been misled by the representations and practices complained of herein. Plaintiff would not have purchased Benecol at the prices he did, or at all, absent reliance on these material representations." *Id.* ¶ 135. Moreover, "Plaintiff altered his position to his detriment and suffered damages in an amount equal to the amount he paid for Benecol," *id.* ¶ 138.

"It hardly needs to be said that many courts have found similar allegations to be sufficient." *Red*, 754 F. Supp. 2d at 1145 (citing *Chavez v. Blue Sky Natural Bev. Co.*, 340 Fed. Appx. 359, 361 (9th Cir. 2009) (allegation that plaintiff "lost money as a result [of defendant's deception] in that he did not receive what he paid for" was "sufficient to allege that Chavez has been injured-in-fact"); *Von Koenig*, 713 F. Supp. 2d at 1078 ("[A] plaintiff may sufficiently allege injury where she contends that she did not receive the benefit of the bargain because a purchased product cost more than similar products without misleading labeling."); *Chacanaca*, 752 F. Supp. 2d at 1125 ("The injury alleged here is the *purchase* of food products that contain an ingredient the plaintiffs find objectionable. Had they known about the trans fat content, they insist, they would not have purchased the product. . . . [P]laintiffs have adequately alleged an injury directly related to the redress they seek.")). *See also Henderson*, 2011 U.S. Dist. LEXIS 41077, at *14-15; *Peviani v. Natural Balance, Inc.*, 774 F. Supp. 2d 1066, 2011 U.S. Dist. LEXIS 18110, at *8-9 (S.D. Cal. Feb. 24, 2011).

McNeil nevertheless argues Plaintiff inadequately pleads reliance on Benecol's label because Mr. Reid supposedly does not allege (1) that he "did not receive what he wanted when buying Benecol," and (2) that Benecol's packaging was consistent throughout the class period. Mot. 21-22.

For its first argument, McNeil contends Mr. Reid fails to plead any facts which, if true, would demonstrate Benecol was something other than a "product that would lower and not negatively affect his LDL and total cholesterol levels." Mot. 22 (citing Compl. ¶ 127).[11] But Mr. Reid alleges:

[11] McNeil does not contest the Complaint sufficiently alleges the Benecol Mr. Reid received differed from the expectation created by its advertising that Benecol "was generally healthy and . . . did not contain any toxic ingredients that would negatively affect his LDL, HDL and total blood cholesterol

> • "Benecol is made with partially hydrogenated vegetable oil (PHVO) containing artificial trans fat, a toxic food additive that, in the amounts present in Benecol, negatively affects blood cholesterol levels to a greater degree than any positive effect associated with plant sterol esters in the product," Compl. ¶ 7;
>
> • "[T]he PHVO in Benecol more than counteracts any positive effect plan stanol esters may have on cholesterol levels, *id.* ¶ 8;
>
> • "By following the directions provided and using 2 servings of Benecol per day, a consumer would not ingest the amount of plant stanol esters that has been determined to be potentially effective in reducing the risk of heart disease," *id.* ¶ 89;
>
> • "[Defendants'] representation, claim and promise that Benecol will reduce cholesterol is false. . . . [T]here are no studies supporting [Defendants] claim that Benecol itself, as formulated . . . is effective in reducing blood cholesterol," *id.* ¶ 94;
>
> • "The trans fat in the PHVO in Benecol has a more substantial negative effect on blood cholesterol levels than any positive effect of the plant stanol esters in Benecol," *id.* ¶ 96; and
>
> • "Instead of receiving a product that has the cholesterol-reducing advantages of plant stanol esters as [Defendants] claim[], Plaintiff received a product made with artificial trans fat, which negatively affects blood cholesterol levels to a greater extent than any positive effect from the plant stanol esters, and in any event negates much of the purported benefit of such plant stanol esters, and exposes Plaintiff to further disease and malady," *id.* ¶ 136.

Aside from these copious factual allegations that, if true, would demonstrate Benecol is not "a product that would lower cholesterol and not negatively affect . . . LDL and total cholesterol levels," McNeil ignores Mr. Reid's allegation that, "even if Benecol reduced cholesterol, the claim would still be highly misleading because, at the level of Benecol consumption needed to achieve that effect, the trans fat a person would consume would expose him or her to increased risk of many other diseases." Compl. ¶ 98. The UCL, FAL and CLRA "prohibit not only advertising which is false, but also advertising which, although true, is either actually misleading or which has a capacity, likelihood or tendency to deceive or confuse the public." *Williams*, 552 F.3d at 938 (internal quotations, citations and alterations omitted).

McNeil also challenges Mr. Reid's reliance on the Benecol label under Rule 9(b), arguing that by supposedly failing to allege Benecol's "packaging was consistent throughout the class period," Mr.

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level and expose him to a greater risk of diabetes, cancer and heart disease." Compl. ¶ 127.

Reid has not shown "when" the label misrepresentations took place. *See* Mot. 22 (citing *Yumul v. Smart Balance, Inc.*, 733 F. Supp. 2d 1117, 1124 (C.D. Cal. May 24, 2010)). Again, McNeil is wrong. Plaintiff alleges that:

> • "[F]or over a decade, [Defendants] ha[ve] packaged Benecol with an improper plant stanol health claim, rendering Benecol misbranded," Compl. ¶ 4;
>
> • "Throughout the class period, [Defendants] ha[ve] always claimed on its labeling that Benecol is *Proven to Reduce Cholesterol*," *id.* ¶ 90; and
>
> • "Throughout the class period, Benecol's packaging contained the representations that Benecol contains *No Trans Fat* or *No Trans Fatty Acids*," *id.* ¶ 108.

Construing the allegations in the light most favorable to Plaintiff, they sufficiently allege the challenged representations were consistent throughout the class period.[12]

4. Mr. Reid Adequately Pleads Reliance Because the Representation that a Product is Proven to Reduce Cholesterol *is Material*

A plaintiff may satisfy the UCL and FAL's causation requirement by demonstrating an alleged misrepresentation is material. Thus, for example, in *In re Toyota Motor Corp.*, the court held "actual reliance may be presumed because. . . the propensity of a vehicle to accelerate suddenly and dangerously out of control is material to a reasonable person, which satisfies the causation requirement under the UCL and FAL." 2011 U.S. Dist. LEXIS 52529, at *125.[13] As in *Toyota*, the

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[12] The plaintiff in *Yumul* cured by amendment the defect that court identified by alleging:

> SBI has not significantly altered the packaging of Nucoa Real Margarine throughout the Class Period, and its marketing of the product on the package has been consistent throughout this time. While certain changes may have been made to the coloring or design of the package during the past 10 years, SBI has consistently touted the purported health benefits of Nucoa Real Margarine and has consistently represented that the product has "No Cholesterol" or is "Cholesterol Free."

See Yumul, No.10-cv-927-MMM (C.D. Cal.), Dkt. No. 20 at ¶ 67.

[13] In a prior decision, the *In re Toyota* court explained:

> Given the fact that an average consumer would not expect an SUA defect, combined with the high costs and risks associated with potential serious accidents, Plaintiffs' allegations are sufficient to demonstrate materiality. The Court agrees. . . that common sense supports Plaintiffs' claim that a potential car buyer would view as material a defect that relates to control over the speed of the car.

In re Toyota Motor Corp. Unintended Acceleration Litig., 754 F. Supp. 2d 1145, 1191 (C.D. Cal

propensity of a product advertised as *Proven to Reduce Cholesterol* to actually *harm* cholesterol and expose those who consume it to increased risk of type-2 diabetes, cancer, cardiovascular disease and death, is material.

B. CLRA

"The CLRA requires a demonstration of actual reliance for standing purposes." *Henderson*, 2011 U.S. Dist. LEXIS 41077, at *16 (citing Cal. Civ. Code § 1780(a)). "However, as discussed in the above section, Plaintiff['s] allegations sufficiently establish actual reliance." *See id.*

V. ALLEGATIONS THAT MCNEIL'S *NO TRANS FAT* CLAIMS ARE FALSE AND MISLEADING SHOULD NOT BE DISMISSED UNDER THE REASONABLE CONSUMER STANDARD

Mr. Reid alleges that, in addition to being misbranded, label claims that Benecol contains *No Trans Fat* and *No Trans Fatty Acids* are false and misleading because Benecol *does* contain trans fat. Compl. ¶ 112. McNeil argues this allegation should be dismissed because an *inside panel* of Benecol's label contains the contradictory explanation that Benecol actually contains "an extremely low level of trans fat." Mot. 23. Because "[a] 'reasonable consumer' is expected to perform a sufficient reading of the packaging or advertising in assessing the assertions made[,]" McNeil contends, "no reasonable consumer could be mislead by the Benecol label's claims," *No Trans Fat* and *No Trans Fatty Acids*. *Id.*

The argument that front-label misrepresentations may be corrected by truthful information elsewhere, however, has been repeatedly rejected since the Ninth Circuit held in *Williams*, "[w]e do not think that the FDA requires an ingredient list so that manufacturers can mislead consumers and then rely on the ingredient list to correct those misinterpretations and provide a shield for liability for the deception." 552 F.3d at 939. *See Yumul*, 733 F. Supp. 2d at 1129 ("*Williams* stands for the proposition that where product packaging contains an affirmative misrepresentation, the manufacturer cannot rely on the small-print nutritional label to contradict and cure that misrepresentation. . . .[T]he court cannot find that this case presents 'the rare situation in which granting a motion to dismiss is appropriate,'" quoting *Williams* 552 F.3d at 939); *Red v. Kraft Foods, Inc.*, 2011 U.S. Dist. LEXIS 2010).

26893, at *10 (C.D. Cal. Jan. 13, 2011); *Chavez v. Nestle USA, Inc.*, 2011 U.S. Dist. LEXIS 9773, at *20 (C.D. Cal. Jan. 10, 2011). But even if McNeil could correct its prominent front-label claims that Benecol contains *No Trans Fat* with contradictory information on an inside panel, Plaintiff also alleges *this* information is also false and misleading, and at this stage the Court assumes this allegation is true. Compl. ¶¶ 116-17.

VI. THERE IS NO BASIS FOR REFERRING THIS ACTION TO THE FDA PURSUANT TO THE PRIMARY JURISDICTION DOCTRINE (OR ABSTAINING)

The doctrine of primary jurisdiction provides that, "[w]hen there is a basis for judicial action, independent of agency proceedings, courts may route the threshold decision as to certain issues to the agency charged with primary responsibility for governmental supervision or control of the particular industry or activity involved." *United States v. Gen. Dynamics Corp.*, 828 F.2d 1356, 1362 (9th Cir. 1987) (citation omitted). Courts prudentially apply the doctrine of primary jurisdiction *only* where there is (1) the need to resolve an issue that (2) has been placed by Congress within the jurisdiction of an administrative body having regulatory authority (3) pursuant to a statute that subjects an industry or activity to a comprehensive regulatory authority that (4) requires expertise or uniformity in administration. *Id.*

Primary jurisdiction "is to be invoked sparingly, as it often results in added expense and delay." *Alpharma, Inc. v. Pennfield Oil Co.*, 411 F.3d 934, 938 (8th Cir. 2005) (citation omitted). At the motion to dismiss stage, when deciding whether to defer jurisdiction, the courts must "apply a standard derived from Rule 12(b)(6) jurisprudence: whether the complaint plausibly asserts a claim that would *not* implicate the doctrine." *County of Santa Clara v. Astra United States*, 588 F.3d 1237, 1251-52 (9th Cir. 2009) (declining to invoke primary jurisdiction where action could "plausibly be adjudicated" without agency's expertise) (citations omitted). *See also Davel Communs., Inc. v. Qwest Corp.*, 460 F.3d 1075, 1088 (9th Cir. 2006) (where "allegations of the complaint do not necessarily require the doctrine's applicability, then the primary jurisdiction doctrine may not be applied on a motion to dismiss").

This action presents issues that are not complex: whether Benecol was misbranded under the FDCA, rendering McNeil liable under the UCL's "unlawful" prong, and whether its advertising is

false and misleading under the UCL, FAL and CLRA. As several courts have found, "[t]he question whether defendants have violated FDA regulations and marketed a product that could mislead a reasonable consumer is one courts are well-equipped to handle, and is not an appropriate basis for invoking the primary jurisdiction doctrine." *Ackerman v. Coca-Cola Co.*, 2010 U.S. Dist. LEXIS 73156, at *54 (E.D.N.Y. July 21, 2010); *see also Mason*, 2010 U.S. Dist. LEXIS 65107, at *4-5 (citation omitted) ("Court[s] are routinely called upon to apply regulations. No technical expertise within the special province of the FDA is necessary for any of the determinations called for in this case."); *Chacanaca*, 752 F. Supp. 2d at 1124 ("[P]laintiffs advance a relatively straightforward claim: they assert that defendant has violated FDA regulations and marketed a product that could mislead a reasonable consumer. . . . [T]his is a question 'courts are well equipped to handle,'" citing *Lockwood*, 597 F. Supp. 2d at 1035 ("[T]his is not a technical area in which the FDA has greater technical expertise than the courts—every day courts decide whether conduct is misleading.")); *Pom Wonderful*, 642 F.2d at 1123 ("Plaintiffs claims are . . . based on state law, which would not necessarily be resolved in the event of an FDA ruling.").[14]

VII. MCNEIL'S MOTION TO STRIKE SHOULD BE DENIED

Allegations are properly stricken *only* where they satisfy one of five conditions enumerated in Rule 12(f), that is, where the allegations are redundant, immaterial, impertinent, scandalous, or where they constitute an insufficient defense. *See Whittlestone, Inc. v. Handi-Craft Co.*, 618 F.3d 970, 973-76 (9th Cir. 2010). "Motions to strike generally will not be granted unless it is clear that the matter to be stricken could not have any possible bearing on the subject matter of the litigation." *In re Facebook PPC Adver. Litig.*, 709 F. Supp. 2d 762, 773 (N.D. Cal. 2010) (citing *LeDuc v. Kentucky Cent. Life Ins. Co.*, 814 F. Supp. 820 (N.D. Cal. 1992)). Moreover, such motions are "not favored and 'should not be granted unless it is clear that the matter to be stricken could have no possible bearing on the subject matter of the litigation.'" *Astiana*, 2011 U.S. Dist. LEXIS 57348, at *34-35 (quoting *Colaprico*

[14] Besides being redundant of its primary jurisdiction argument, McNeil's abstention argument is also misplaced. "[T]he United States Supreme Court recognizes four federal abstention doctrines – Pullman, Burford, Colorado River, and Younger. None of these involve 'abstention' by a federal court in favor of deferring to a federal agency." *Astiana*, 2011 U.S. Dist. LEXIS 57348, at *27-28 (citing *United States. v. Morros*, 268 F.3d 695, 703-09 (9th Cir. 2004)).

v. Sun Microsystem, Inc., 758 F. Supp. 1335, 1339 (N.D. Cal. 1991)). In considering a motion to strike, courts must "view the pleading in a light most favorable to the pleading party," and "deny the motion . . . if there is any doubt whether the allegations in the pleading might be relevant in the action." *Id.* *35 (citation omitted).

A. Information Relating to the Misleading Nature of Benecol's Advertising

Although McNeil asks the Court to strike 58 paragraphs—a third of the Complaint—it does not identify under what prong of Rule 12(f) it seeks relief. Instead, citing *Facebook*, McNeil asserts these are "allegations supplying background or historical material," Mot. 23. Such allegations "will not be stricken unless unduly prejudicial to defendant." *Facebook*, 709 F. Supp. 2d at 773 (denying motion to strike where defendant failed to show undue prejudice) (citing *LeDuc*, 814 F. Supp. at 830).

The allegations McNeil wants stricken are not immaterial. These allegations explain how cholesterol affects health, Compl. ¶¶ 17-26; why the artificial fat in Benecol is so dangerous and how it counteracts the positive effects of plant stanol esters, *id.* ¶¶ 27-66; and how plant stanol esters work, *id.* ¶¶ 67-74. The allegations also include the composition of Benecol's plant stanol esters. *Id.* ¶ 73. These are not "background or historical" material, but information crucial to Plaintiff's claims that Benecol's advertising is misleading. Because these allegations "when read with the complaint as a whole, give a full understanding thereof, they need not be stricken." *See LeDuc*, 814 F. Supp. at 830 (citation omitted). Indeed, several courts have referred to similar allegations in providing background as parts of decisions concerning products made with trans fat alleged to be unlawfully advertised. *See, e.g., Peviani v. Hostess Brands, Inc.*, 750 F. Supp. 2d 1111, 1114 (C.D. Cal. 2010); *Chacanaca*, 752 F. Supp. 2d at 1115; *Red*, 2010 U.S. Dist. LEXIS 115238, at *3-4; *Yumul*, 733 F. Supp. 2d at 1135-36; *Ctr. for Sci. in the Pub. Interest v. Burger King Corp.*, 534 F. Supp. 2d 141, 142 (D.D.C. 2008); *Jernow v. Wendy's Int'l, Inc.*, 2007 U.S. Dist. LEXIS 85104, at *3 (S.D.N.Y. Nov. 15, 2007).

But even if these allegations were "superfluous," Mot. 23, McNeil has not demonstrated undue prejudice because its unsupported assertion that it will have to "engage scientific and medical experts to determine the veracity of each assertion," *id.* 24, is wrong. Because the Federal Rules permit a defendant to answer allegations by stating the defendant "lacks knowledge *or information* sufficient to form a belief," Fed. R. Civ. P. 8(b)(5), a defendant need not affirmatively seek out information not

currently in its possession in order to answer. Moreover, McNeil is a company that markets a product containing artificial trans fat that is purported to "reduce cholesterol" because of its plant stanol esters. The assertion that McNeil will have to hire experts to answer allegations about cholesterol, trans fat, and plant stanol esters is therefore improbable. *C.f. SG Supply v. Greenwood Int'l, Inc.*, 1992 U.S. Dist. LEXIS 386, at *19 (N.D. Ill. Jan. 10, 1992) ("Rule 8(b) teaches (1) the critical factor for a party seeking the benefit of a deemed denial is his or her *belief*, rather than out-and-out knowledge, as to whether or not an allegation is true and (2) *information* may be enough to support a belief that the allegation is true.").

B. Allegations that Benecol is a "New Drug"

In addition to failing to identify the basis under Rule 12(f) on which to strike "Plaintiff's claim that Benecol is a misbranded drug," Mot. 24, McNeil fails to identify the material it wants stricken. *See id.* 24-25. Instead, McNeil ignores the regulations cited in the Complaint and makes a misguided argument that Benecol complies with regulations, and is not a drug, but a food. *Id.* Allegations that Benecol's labeling violates FDA regulations is material to Plaintiff's UCL, FAL and CLRA claims and should not be stricken. McNeil's argument that Benecol is not a drug because its labeling complies with FDA regulations is improper on a motion to strike, and should have been made as part of its motion to dismiss. *See, e.g.*, *Nimtz v. Cepin*, 2011 U.S. Dist. LEXIS 21104, at *14 (S.D. Cal. Mar. 3, 2011) (Lorenz, J.).

But even if the Court construes McNeil's motion to strike the "new drug" allegations in the Complaint as a preemption argument under Rule 12(b)(6), it should deny the motion because the Complaint adequately alleges, and a jury could find, that McNeil promotes Benecol for conditions that cause the product to be a drug under the Act. As paragraph 101 of the Complaint alleges:

> The regulatory classification of a product under the FDCA is determined by its intended use, as evidenced by, among other things, its labeling and advertising, the circumstances of its marketing, sale and use, and the manufacturer's knowledge that a product is being used for a purpose for which it is neither labeled nor advertised. *See* 21 C.F.R. § 201.128.

Pursuant to 21 U.S.C. § 321(g)(1), "products that are intended to affect the structure or function of the body, or for use in the diagnosis, cure, mitigation, treatment, or prevention of disease," are drugs. The FDA has held the labeling or advertising of all the following foods also rendered them

drugs under the Act: oat cereal,[15] soy milk,[16] olive oil,[17] walnuts,[18] tea,[19] bread,[20] juice,[21] and sprouts.[22] In determining these foods were illegally-marketed new drugs, the FDA relied on labeling and web advertisements like:

- "*green tea: . . .* ***reduces total cholesterol and LDL (bad cholesterol)***," RJN Ex. H (Ten Ren Tea Company Letter);
- Product's Vitamin B3 content is "***Known to . . . reduce the cholesterol level in the blood***," RJN Ex. K (FUZE Beverages Letter);
- "***Helps lower high cholesterol***," RJN Ex. M (Shemshad Letter);
- Product "*is a natural cholesterol controller which* ***helps to reduce bad cholesterol***," RJN Ex. N (Universal Taste Letter);
- *"full of phytochemicals . . . that are powerful allies in . . .* ***lowering cholesterol levels***," RJN Ex. P (Jonathan's Sprouts Letter); and
- In section titled "Cholesterol Research," claim that "*four recent studies in people at risk for coronary heart disease have shown* ***a significant cholesterol lowering effect*** *from tea or tea flavonoids . . . .*" RJN Ex. I (Unilever Letter).

Accordingly, McNeil's contention that "under FDA's regulatory framework, Benecol is a food not a drug," and that Plaintiff's allegations are "illogical and contrary to the regulatory scheme," Mot. 25, is erroneous. Like these products, Benecol's label, website,[23] and advertising practices demonstrate that it

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[15] *See* Cheerios Letter, RJN Ex. C.

[16] *See* BestLife Letter, RJN Ex. A.

[17] *See* RJN Ex. D (FDA Warning Letter to Pompeian, dated February 22, 2010).

[18] *See* RJN Ex. E (FDA Warning letter to Diamond Food, dated February 22, 2010).

[19] *See* RJN Ex. F (FDA Warning Letter to Diaspora Tea & Herb Co., dated April 20, 2011); Ex. G (FDA Warning Letter to Grinalat Foods Corporation, dated July 13, 2006); Ex. H (FDA Warning Letter to Redco Foods, dated Feb. 22, 2010); Ex. I (FDA Warning Letter to Ten Ren Tea Company of San Francisco, dated May 6, 2011); Ex. J (FDA Warning Letter to Unilever, dated August 23, 2010).

[20] *See* RJN Ex. K (FDA Warning Letter to French Meadow Bakery, dated April 13, 2005).

[21] *See* RJN Ex. L (FDA Warning Letter to FUZE Beverages dated December 18, 2006); Ex. M (FDA Warning Letter to POM Wonderful, dated February 23, 2010); Ex. N (FDA Warning Letter to Shemshad Food Products, dated March 11, 2011); Ex. O (FDA Warning Letter to Universal Taste, dated August 7, 2009).

[22] *See* RJN Ex. P (FDA Warning Letter to Jonathan's Sprouts, dated March 24, 2011).

[23] The URL for Benecol's website appears repeatedly on Benecol's label. *See* Compl. Exs. A-D. Accordingly, it is labeling pursuant to 21 U.S.C. § 321(m). *See* Cheerios Letter, RJN Ex. B ("We have determined that your website www.wholegrainnation.com is labeling for your Cheerios® product

is promoted for use in the prevention, mitigation and treatment of hypercholesterolemia. *See* Compl. ¶¶ 88, 93, 102-103, 121, 123. But Benecol is not generally recognized as safe and effective in treating hypercholesterolemia. Therefore, it is a new drug pursuant to 21 U.S.C. § 321(p). New drugs, besides being misbranded, may not be legally marketed in the United States without prior approval from the FDA as described in 21 U.S.C. § 355(a). When such products are unlawfully marketed, like Benecol, they are also misbranded pursuant to 21 U.S.C. § 352(f)(1) because their labeling necessarily fails to bear adequate directions for use.

C. The Prayer for Relief Cannot be Stricken Under *Whittlestone*

This relief is not authorized by Rule 12(f) . *Whittlestone* 618 F.3d at 973-76 ("We hold that Rule 12(f) . . . does not authorize a district court to dismiss a claim for damages on the basis that it is precluded as a matter of law.").

CONCLUSION

The Court should, respectfully, deny McNeil's Motion to Dismiss; however, to the extent the Court is inclined to grant any portion of the motion, Plaintiff respectfully requests that dismissal be without prejudice, and with leave to amend.

Dated: September 2, 2011

By: /s/ Jack Fitzgerald
Jack Fitzgerald

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under section 201(m) of the Act [21 U.S.C. § 321(m)] because the website address appears on the product label."). *Accord* Compl. ¶¶ 119-20.